



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,446	08/01/2003	Igal Madar	1856-SPL	4685

26085 7590 11/17/2006

THE JOHNS HOPKINS UNIVERSITY APPLIED PHYSICS LABORATORY
OFFICE OF PATENT COUNSEL
11100 JOHNS HOPKINS ROAD
MAIL STOP 7-156
LAUREL, MD 20723-6099

EXAMINER

SHAHRESTANI, NASIR

ART UNIT	PAPER NUMBER
----------	--------------

3737

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,446

Applicant(s)

MADAR ET AL.

Examiner

Nasir Shahrestani

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/1/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24 is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-50 is/are rejected.
- 7) ☒ Claim(s) 1-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 27-50 are objected to because of the following informalities: Claim 27 of the application is repeated and the remaining claims are hence numbered incorrectly. Examiner has in accordingly addressed the claims in consecutive numbering (e.g. claim 50 is now referred to as claim 51). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the animal" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 13, 25-28, 37-42, 46-49, and 51, are rejected under 35 U.S.C. 102(b) as being anticipated by Crowley et al. (U.S. Patent No.: 6,324,418).

Regarding claims 1-3, 5-6, 13, Crowley et al. teaches a method for detecting fluorescence emitted in a wall of a body lumen (column 6 lines 29-33) comprising the steps of introducing a solid support into a body lumen (fig. 3) being autonomous since it is navigated through the patients anatomy; illuminating cells in a lumen from a light source mounted to the solid support with a wavelength that excites a fluorescent signal (column 2 lines 1-10; column 6 lines 46-54); detecting at a detector whether the illuminated cells emit the fluorescent signal (column 2 line 2) and determining at least one of an intensity and a position in the lumen wall of the detected fluorescent signal (column 1 lines 65-66). Crowley further teaches generating an image that indicates positions in the lumen wall (column 5 lines 7-15). The reference further teaches that the detected fluorescent signal indicates presence or absence of cancerous cells (column 3 lines 19-33). Furthermore Crowley teaches a wireless power transfer system (power

source 15), a position control module or system (control module 19) for manipulation and modulating carrier waves.

Regarding claims 25-28, 37-42 Crowley et al. teaches a capsule (fig. 2A) comprising a solid support that fits inside a along an inner circumference of body lumen (fig. 3), light source (column 2 line 2) for generating a light with a wavelength that excites fluorescent signal in certain molecules (column 6 lines 46-54); a first optical element (distal window 5); a detector and second optical window for directing light to said detector, both mounted to the solid support (light detectors 6b; column 5 lines 16-29); and a data transfer system (transmitter 20) for transferring data based on measurements taken from the detector (column 6 lines 38-45) to a monitoring unit outside (see abstract). Crowley et al. further teaches the second optical element comprising a filter also construed to be a shutter for blocking extraneous and unwanted wavelengths of light (see claim 1; column 6 lines 38-45). Furthermore Crowley teaches a single or array of sensors that distinguish light intensity, inherently over different periods of time (fig. 2A, sensors 17; column 5 lines 7-15). Crowley et al. further teaches generating an image based on illuminated measurements (column 1 lines 65-66) wherein said image is inherently processed by a processor and said image is inherently processed into pixels that represent intensity of illuminated sections.

Regarding claims 48-49, 51, Crowley et al. teaches a monitoring unit comprising a receiver for receiving data (fig. 2B) that fits inside that capsule, said solid capsule including a light source (column 2 line 2) mounted to the solid support an a detector (column 2 line 2) mounted to the support for generating measurements based on a fluorescent signal emitted from the lumen wall (column 6 lines 38-45) and a data transfer system (transmitter 20), a display for

presenting the image to a user inherently containing a processing to generate said image data (see abstract). Said receiver as taught by Crowley et al. is configured to obtain measurements based on position of the capsule inherently comprising a processing system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7-10, 43, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Daighighian et al. (U.S. Pub. No.: 2002/0168317).

Crowley teaches all the limitations of claim 1 as described above but fails to teach wherein the method further includes introducing exogenous fluorescent-labeled probe from a reservoir injected into a body that binds to cells in the lumen wall resulting in fluorescent emission. Daighighian et al. teaches the aforementioned limitations of claim 4 relating to cell labeling using a probe sensitive to the presence of label applied to the cell (abstract; par.[0002]). Furthermore, Daighighian et al. teaches the use of annexin-V as the exogenous probe for the purpose of labeling the cell for fluorescent emission (par. [0041]) from a reservoir (PFR 528). It would have been obvious to one of ordinary skill in the art to have modified the method of cell detection as taught by Crowley et al. and to have included an exogenous fluorescent labeled

probe as taught by Daighighian et al. comprising annexin-V in order to radio-label dead or damaged cells so that the location of the cells can be detected.

Claims 11, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Daighighian et al. (U.S. Pub. No.: 2002/0168317) and in further view of Rodriguez et al. (U.S. Pub. No.: 2004/0049148).

Crowley et al. in view of Daighighian et al. teaches all the limitation of claim 10 as described above but fails to teach the step of emitting ultrasonic waves from a sound source on the solid support to enhance uptake of the drug. Rodriguez et al. teaches the aforementioned limitation of enhancement of drug intake by the cells by emitting ultrasonic waves from a sound source (par.[0096]). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Crowley et al. in view of Daighighian et al. and to have further included the emission of ultrasonic wave to enhance drug uptake. Such ultrasound energy is an additional feature that facilitates greater control over the movement of the drugs, enhances the uptake of drugs and other therapeutic effects.

Claims 12, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Daighighian et al. (U.S. Pub. No.: 2002/0168317) and in further view of Reed et al. (U.S. Patent No.: 6,197,013).

Crowley et al. in view of Daighighian et al. teaches all the limitations of claim 14 as described above but fails to teach the step of generating an electric field from an electrode on the solid support to enhance uptake of the drug. Reed et al. teaches the aforementioned limitation of enhancement of drug intake by the cells by producing electric fields (column 13 lines 21-46). It would have been obvious to one of ordinary skill in the art at the time of the invention to have

Art Unit: 3737

modified the method as taught by Crowley et al. in view of Daighighian et al. and to have further included the generation of an electric field from an electrode to enhance drug uptake. Such electrical means is an additional feature that facilitates greater control over the movement of the drugs.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Takizawa et al. (U.S. Pub. No.: 2003/0020810) and in further view of Gazdzinski (U.S. Patent No.: 6,984,205).

Crowley et al. in view of Takizawa et al. teaches all the limitations of claims 1 and 4 as described above but fails to teach the releasing a drug that kills the detected abnormal intestinal cells. Gazdzinski teaches a capsule (fig. 11) that is capable of drug delivery, released inherently from a reservoir, within the GI and specifically the intestinal track (column 17 lines 44-59). It would have been obvious to one of ordinary skill in the art to have modified the method as taught by Crowley et al. in view of Takizawa et al. and to have further included the method of releasing a drug that kills the abnormal intestinal cells as taught by Gazdzinski in order to minimize the amount of time spend from the point of illuminating the abnormal cell to the point of treatment or "killing" of the cell using a drug delivery mechanism.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Takizawa et al. (U.S. Pub. No.: 2003/0020810), Gazdzinski (U.S. Patent No.: 6,984,205), and in further view of Rodriguez et al. (U.S. Pub. No.: 2004/0049148).

Crowley et al. in view of Takizawa et al. and Gazdzinski teaches all the limitations of claim 14 as described above but fails to teach the step of emitting ultrasonic waves from a sound source on the solid support to enhance uptake of the drug. Rodriguez et al. teaches the aforementioned limitation of enhancement of drug intake by the cells by emitting ultrasonic waves from a sound source (par.[0096]). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Crowley et al. in view of Takizawa et al. and Gazdzinski and to have further included the emission of ultrasonic wave to enhance drug uptake. Such ultrasound energy is an additional feature that facilitates greater control over the movement of the drugs, enhances the uptake of drugs and other therapeutic effects.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Takizawa et al. (U.S. Pub. No.: 2003/0020810), Gazdzinski (U.S. Patent No.: 6,984,205), and in further view of Reed et al. (U.S. Patent No.: 6,197,013).

Crowley et al. in view of Takizawa et al. and Gazdzinski teaches all the limitations of claim 14 as described above but fails to teach the step of generating an electric field from an electrode on the solid support to enhance uptake of the drug. Reed et al. teaches the aforementioned limitation of enhancement of drug intake by the cells by producing electric fields (column 13 lines 21-46). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Crowley et al. in view of Takizawa et al. and Gazdzinski and to have further included the generation of an electric field

form an electrode to enhance drug uptake. Such electrical means is an additional feature that facilitates greater control over the movement of the drugs.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Takizawa et al. (U.S. Pub. No.: 2003/0020810) and in further view of Tachibana et al. (U.S. Patent No.: 6,176,842).

Crowley et al. in view of Takizawa et al. teaches all the limitations of claims 1 and 4 as described above but fails to teach at least one probe bound to a light activated toxin, nor does it teach if the particular fluorescent signal is detected, then illuminating the cells with light to activate the light-activated toxin to kill the abnormal cells. Tachibana et al. teaches the aforementioned limitations of claim 20 comprising light activated toxins from the group of photofrin and the method of activating said toxins upon illumination of cells (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Crowley et al. in view of Takizawa et al. and to have further included the method of labeling the cells with a light activated toxin and illuminating said toxin as taught by Takizawa et al. since the activation of the light activated toxin/drug causes tissue death within the tissue site.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Takizawa et al. (U.S. Pub. No.: 2003/0020810). Crowley et al. teaches all the limitations of claims 27 and 25 as described above but does not teach a transparent band in an outer cover of the solid support. Takizawa et al. teaches a capsule having a transparent band in an outer cover of the solid support (par. [0099]). It would have

been obvious to one of ordinary skill in the art at the time of the invention to have modified the capsule as taught by Crowley et al. and to further include a transparent band as taught by Takizawa in order to provide for better and wider spectrum of illumination of cells of interest within a body lumen.

Claims 30-31, 33-35 are rejected over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Iddan et al. (U.S. Patent No.: 5,604,531).

Crowley et al. teaches all the limitations of claims 25 and 28 as described above fails to teach a first and second optical element comprising an axicon to convert bands of light going out and coming in from said solid support, nor does it teach a coherent bundle of optical fibers that causes multiple radial beams of light to pass through. Iddan et al. teaches the aforementioned limitation of a capsule comprising an axicon in order to direct a beam either coming from a light source or reflected from an illuminated site back into said capsule (column 2 lines 11-33). Furthermore, Iddan teaches a bundle of optical fibers in order to direct beams of illumination (column 1 lines 40-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the capsule as taught by Crowley et al. and to have further included an axicon in order to produce a perpendicular object and the axicon enables a lens unit to form an image on the detector when perpendicular to the optical axis. Furthermore, in accordance with another embodiment of the invention, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the capsule as taught by Crowley et al. and to have further included a bundle of optical fibers in order to direct a beam in

and out of the solid capsule since the optical fibers flexible nature would prevent the need for other means of redirection of light.

Claims 32 and 36 are rejected over Crowley et al. (U.S. Patent No.: 6,324,418) in view of Hochrainer et al. (U.S. Patent No.: 6,949,154).

Crowley et al. teaches all the limitations of claims 25 and 28 as described above but fails to teach a first and second optical element comprising a rotating mirror that reflects a light pulse on an axial beam from the light source to a rotating radial beam that passes through the transparent band, nor does it teach one reflects in turn multiple radial beams of light that pass through the transparent band from the illuminated section of the lumen wall onto the detector. Hochrainer et al. teaches a means for a beam to be guided around the capsule by means of rotating mirrors (fig. 15; column 11 lines 6-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the capsule as taught by Crowley et al. and to have further included rotating mirrors as taught by Hochrainer et al. in order to allow the angle of rotation and the illuminated target to be synchronized.

Allowable Subject Matter

Claims 22-24 are allowed. The prior art of record teaches limitations of claims 22-24 but fails to teach steps (d) and (e) of claim 22 pertaining to set method nor does it teach determining of efficacy. Regarding claims 23-24, the prior art of record fails to teach two separate and distinct solid supports.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nasir Shahrestani
11/10/2006


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700